UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,983	04/15/2004	G. Ian Rowlandson	146462IT (5024-00124)	7541

26753 7590 05/21/2007

ANDRUS, SCEALES, STARKE & SAWALL, LLP
100 EAST WISCONSIN AVENUE, SUITE 1100
MILWAUKEE, WI 53202

EXAMINER	
REIDEL, JESSICA L	
ART UNIT	**PAPER NUMBER**
3766	
MAIL DATE	**DELIVERY MODE**
05/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary	Application No.	Applicant(s)	
	10/824,983	ROWLANDSON ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-8,10,12-20,41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-8,10,12-20,41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 December 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of Applicant's Amendment, which was received by the Office on March 13, 2007. Claims 5, 9, 11 and 21-40 are cancelled. Claims 1-4, 6-8, 10, 12-20 and 41-42 are pending.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: "Method for Assessing a Patient's Risk of Sudden Cardiac Death".

Claim Objections

3. Claim 10 is objected to because of the following informalities: there appears to be an inadvertent typographical error in the claim. The Examiner suggests modifying the dependency of Claim 10 such that the claim depends from Claim 1 sine Claim 9 has been cancelled by Applicant's Amendment. Appropriate correction is required.

Allowable Subject Matter

4. The indicated allowability of claims 11-12 and 42 is withdrawn in view of the newly discovered reference(s) to Erkkila et al. (U.S. 2004/0215090) (herein Erkkila) Bayer et al. (U.s. 2002/0133087) (herein Bayer) and Krass (U.S. 6,517,480). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 10, 14 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As to Claims 10 and 41, specifically, the Examiner is unsure if Applicant's "threshold" is different from the Applicant's "probability constant". The Examiner makes specific reference to Applicant's disclosure pages 12-13 and Applicant's Fig. 2. The Examiner suggests modifying the language of Claim 10 to read something similar to "and further comprising alerting a healthcare provider if the probability of sudden cardiac death is greater than the probability constant". Claim 41 should be modified similarly in order to overcome the 35 U.S.C. 112, 2nd paragraph rejections against it.

7. Claim 14 recites the limitation "the measurements" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 14 recites the limitation "the blood pressure" in the third line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 1-4, 6, 8, 10, 12-20 and 41-42 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, Applicant's claims are directed to a judicial exception of 35 U.S.C. 101. The method claims of the present application relate to abstract ideas, rather than practical applications of those ideas. Specifically, the claims do not require any physical transformation and the invention as claimed does not produce a useful, concrete, and tangible result. See MPEP § 706.03(a). To

overcome this rejection, the Examiner recommends adding a tangible, useful and concrete method step wherein the method "employs" the "comparing" by "performing an action" or "completing a method step" using a device/system of some sort. For example, addition of limitations involving a designation of risk level being stored in the MUSE system (see page 12, paragraph 36 of Applicant's disclosure) or even addition of the limitations of dependent Claim 7 into the independent claims would overcome the 35 U.S.C. 101 rejections against Claims 1-4, 6, 8, 10, 12-20 and 41-42.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erkkila in view of Bayer. As to Claims 41-42, Erkkila expressly discloses a method of assessing a risk of sudden cardiac death for a patient (see Erkkila Abstract) comprising identifying a patient as

being worthy of an on-going sudden cardiac death risk assessment when the patient arrives at a hospital (steps 301 and 302) and performing the on-going sudden cardiac death assessment whenever new patient data (i.e. new measured signal parameters) is/are acquired at a sever 605 (see Erkkila pages 4-5, paragraphs 59-60). Server 605 of Erkkila exists as one of a plurality of healthcare locations. Bedside apparatus (see Erkkila Fig. 6) exists as another one of a plurality of healthcare locations. Erkkila specifies that a probability of sudden cardiac death for the patient is calculated as a sudden cardiac death risk index (SCDRI) and further that the SCDRI is based on the new patient data, specifically the newly measured signal parameters received at server 605 from the bedside monitor (see Erkkila page 1, paragraph 2, page 2, paragraphs 14-29 and page 5, paragraph 60). The method of Erkkila includes comparing the SCDRI to a reference or threshold value set at step 303 where the reference or threshold value depends on an initial calculation of SCDRI. The Examiner considers the reference or threshold value of Erkkila synonymous with the at least one probability constant specific for the patient of Applicants. Erkkila expressly discloses that a healthcare provider is alerted if the probability of sudden cardiac death, i.e. the SCDRI is greater than the reference or threshold which is a probability constant specific to the patient (see Erkkila page 3, paragraphs 42-45 and pages 4-5, paragraphs 60-65).

Erkkila expressly discloses the claimed invention as discussed above except that it is not specified that the identification of the patient being worthy of an on-going sudden cardiac death risk assessment be based on acquired patient data where the patient data is acquired at one of a plurality of healthcare locations. It is inherent, or at least obvious to one having ordinary skill in the art at the time the invention was made that a nurse or physician would "acquire data from the

patient" upon the patient's arrival at the hospital (i.e. while the patient is in the emergency room) in order to determine whether or not it is necessary to perform the sudden cardiac death risk assessment as previously discussed, otherwise the method of Erkkila would be performed on a plurality of patients where determining an SCDRI is unnecessary. Specifically, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Erkkila with the steps of acquiring the patient's symptoms which brought the patient to the hospital and subsequently identifying that patient as being worthy of the on-going sudden cardiac death risk assessment based on that acquired data since it was known in the art that specific symptoms, such as a patient reporting chest pains, read as a pre-existing condition are used to reliably decide whether or not to assess a patient for the possible risk of heart attack. The Examiner provides Bayer as evidence of the conventionality of these steps (see Bayer page 3, paragraph 28).

14. Claims 1-4, 6-8, 10, 12-15, 17-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erkkila in view of Bayer and Krass. As to Claims 1-2, 10, 12, 15 and 17, Erkkila teach that a user interface 704 (display and control input) of the bedside monitor (see Erkkila Figs. 6-7) is provided which allows a nurse to operate the bedside monitor for performing the method of assessing a risk of sudden cardiac death for a patient (see Erkkila page 5, paragraph 62). The previously modified Erkkila reference discloses the claimed invention except that it is not specified that a sudden cardiac death risk assessment tool be accessed via an icon displayed on a patient monitor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and bedside apparatus as taught by Erkkila such that a user (i.e. the nursing staff) may press a start icon of a touch screen user

interface since it was known in the art to provide a touch screen user interface for simplicity of control of a testing apparatus and to integrate a display and control input into one device. The Examiner provides Krass as evidence of the conventionality of this type of feature (see Krass column 4, lines 50-62).

15. As to Claim 3, Erkkila discloses the claimed invention as discussed above except the reference is silent to the exact phrase "automatic". Erkkila does not specify that the on-going sudden cardiac death risk assessment be performed automatically. It would have been obvious to one having ordinary skill in the art at the time the invention was made to automatically perform the on-going sudden cardiac death risk assessment, since it has been held that broadly providing a mechanical or automatic means to replace manual activity, which has accomplished the same result, involves only routine skill in the art.

16. As to Claim 4, the method of Erkkila further includes acquiring both cardiological and non-cardiological patient data (see Erkkila page 4, paragraphs 50-58).

17. As to Claim 6, it is inherent that the method of Erkilla comprises acquiring patient data at an emergency room since it is specified that the method applies to monitoring a hospitalized patient in acute care (see Erkilla page 3, paragraph 39) and further since Erkilla specifies that the sudden cardiac death risk assessment is started once the patient arrives at the hospital (see Erkilla Fig. 3 and page 3, paragraph 44). Erkilla also specifies that in alternative embodiments the invention may be used in care areas such as ambulatory care, nursing homes and in home care (see Erkilla page 5, paragraphs 64-65).

18. As to Claim 7, in addition to the arguments previously presented, Erkilla expressly discloses that the SCDRI is displayed on a patient monitor 604 located at one of a plurality of healthcare locations (see Erkilla Fig. 6 and page 5, paragraph 59).

19. As to Claim 8, Erkilla discloses that acquired data may be stored in a database, read as hospital information system 606 and further that a server 605 accesses the acquired patient data from the hospital information system in order to perform the sudden cardiac death risk assessment (see Erkilla page 5, paragraph 60).

20. As to Claim 13, Erkilla expressly discloses that performing the on-going sudden cardiac-death risk assessment is based on an electrocardiogram (see Erkilla Figs. 1-4 and page 4, paragraph 54).

21. As to Claim 14, Erkilla expressly discloses that the method may further comprise performing the on going sudden cardiac death risk assessment based on measurements including blood pressure measurements (see Erkilla Figs. 1-3 and Fig. 5 and page 4, paragraphs 55-58).

22. As to Claim 18, Erkilla specifies that laboratory results may be manually selected as an input parameter upon which the on going sudden cardiac death risk assessment is performed (see Erkilla page 4, paragraph 58).

23. As to Claim 20, Erkilla expressly discloses that the method further comprises performing the on going sudden cardiac death risk assessment based upon cardiological patient data such as heart rate variability, an arrhythmia, rhythm abnormalities, repolarization phase analysis, late potentials and/or conduction abnormalties (see Erkilla Fig. 4, page 2, paragraphs 14-29 and page 4, paragraphs 50-54).

24. Claims 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erkkila in view of Bayer and Krass as applied to claim 1 above, and further in view of Lozier et al. (U.S. 2004/0230456) (herein Lozier). Erkkila specifies that the method may be implemented as part of the local area network (LAN) of the hospital for transferring the signal parameters to a centralized server 605 (see Erkkila page 5, paragraph 60). The previously modified Erkkila reference discloses the claimed invention as discussed above except that it is not specified that the method include flagging an identification associated with a patient if the patient is worthy of an on-going sudden cardiac death risk assessment. Lozier, however, teaches a software system for identifying patients who may be appropriate candidates for implementation with an implantable cardioverter/defibrillator (ICD) where the software system is implemented on a clinical data manager 102 of a hospital network 103. Lozier discloses comprises flagging (via color coding, a patient's name or secret coding) identification associated with the patient if the patient is worthy of an on-going sudden cardiac death risk assessment in order to identify one patient among a plurality of patients in a hospital network (see Lozier page 1, paragraph 9, page 2, paragraph 12 and page 3, paragraphs 18-19). Lozier discloses that a user may sort the patient records in a desired order based upon the values contained in particular data fields (such as sudden cardiac risk data field 205). The Examiner takes the position that when patient profiles/records are listed in hierarchical order such as this, each profile adjacent to each other in the list would at least partially match (see Lozier pages 2-3, paragraph 16-20). It would have been obvious to one having ordinary skill in the art to modify the network of the previously modified Erkkila reference to include the clinical data manager of Lozier such that patients who

are at risk and may be eligible for ICD may be easily identified within the hospital information system.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jessica L. Reidel 05/17/07
Patent Examiner
Art Unit 3766

Carl H. Layno
Primary Patent Examiner
Art Unit 3766

CARL LAYNO
PRIMARY EXAMINER
ACTING SPE, AU 3766